# SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING MAY 22 -23, 2001

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, May 22, 2001, at 1:00 p.m. and on Wednesday, May 23, 2001, at 8:00 a.m. and 1:00 p.m. Mountain Daylight Time (MDT) as part of the Seventh NELAC Annual Meeting in Salt Lake City, UT. The meeting was led by its chair, Mr. Scott Siders of the Illinois Environmental Protection Agency. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss proposed changes to Chapter 5 and other items on the committee's agenda.*

## INTRODUCTION - SESSION 1

Mr. Scott Siders introduced himself, and each of the committee members introduced themselves. Mr. Mike Beard reviewed the ground rules for the session. Mr. Siders discussed the history of the Quality Systems chapter of the NELAC Standard and gave an overview of agenda items and issues to be covered during the meeting.

## INTEGRATION OF ISO/IEC 17025
## PRESENTATION BY THE ISO/IEC 17025 SUBCOMMITTEE

Dr. Fred Siegelman of the U.S. Environmental Protection Agency (EPA) went over the agenda for presentations pertaining to the International Organization for Standardization (ISO) 17025; the overheads are shown in Attachment C. He also gave a history of the Quality Systems Chapter and how they have arrived at the point they are today. The previously formed ISO 17025 subcommittee had identified three areas for discussion:

1. should standard be consistent or independent of 17025,
2. should standard include language from 17025 or reference 17025, and
3. should the standard be organized like 17025 or the current NELAC Standard.

Dr. Siegelman identified issues pertaining to the direct use of language from ISO 17025. The main concern is a copyright issue and the Board of Director's (BoD) consideration of fees associated with directly citing the standard.

The final issue addressed concerned reorganization of Chapter 5. Two alternatives were presented including rearranging Chapter 5 to be more consistent with ISO 17025 or maintaining the current chapter order. Pros and Cons of the two alternatives are given in Attachment C.

At the end of the discussion an unofficial poll was taken of the attendees on each of theses issues. Polling showed unanimous support for a standard consistent with an international standard; 62 attendees supported inclusion of ISO 17025 language while 15 indicated a preference for referencing ISO 17025. In a second poll, 85 attendees supported reorganization of the standard consistent with ISO 17025 while 2 did not want to change the current organization.

**Statistical Concepts - Relevent Terms**

Ms. Marlene Moore discussed basic statistical concepts used in evaluating precision and bias of data associated with ISO 17025. The overheads used in this presentation are also included in Attachment C. She noted numerous documents dealing with this subject most of which used different terms. Relevant terms were introduced such as absolute uncertainty, relative uncertainty, method uncertainty, uncertainty of measurement, and expanded uncertainty. Ms. Moore discussed the new concept of nested uncertainty which estimates the uncertainty based on a single measurement and incorporates sampling and laboratory effects. She stated that the Quality Systems Committee must look at the new information that is available and offered a paper on this nested approach which is currently under peer review.

Discussion

It was questioned whether the BoD will be willing to pay for ISO 17025 language. The committee indicated that the BoD would have to address the issue of costs related to using text from ISO 17025.

A participant asked when must this be implemented and could one option be to delay the incorporation until it is known if there would be changes to ISO 17025. Dr. Siegelman replied that he was unsure as to how long we could wait. The committee hopes to have it incorporated by the next annual meeting. Ms. Moore added that 17025 is bothersome because it is not consistent with ISO 9000. International accrediting bodies have agreed that all aspects of 17025 must be implemented by 2002 in order for laboratories to be internationally accredited.

A participant suggested that as long as the NELAC Standard is consistent with ISO 17025 it would accomplish the goals for laboratories in the short term. Mr. Siders stated that whether the ISO 17025 should be referenced, exact language used, or not used at all is another question for the BoD.

Another participant stated that their laboratory used both ISO 17025 and NELAC Standard documents and wrote a quality assurance (QA) plan that incorporates both. They did not find it difficult to write the QA plan although it would have been helpful if terminology was consistent between the two. Her laboratory excluded the information on uncertainty as they were unsure as to how to address uncertainty with the results clustered around regulatory limits such as maximum contaminant levels (MCLs). Mr. Siders responded that regulatory agencies may want to address the issue of uncertainty.

It was suggested by another participant that the NELAC Standard be restructured so that it flows similarly to the way QA plans are written so that implementation of the Standard is made easier .

Dr. Bart Simmons of California discussed how California will handle uncertainty. He added that it would be very helpful to record the confidence intervals and systematic error. Mr. Siders responded that this was a good idea but implementing it would take training.

Ms. Jackie Sample of U.S. Navy believes that the reorganizational approach of 17025 would be much more beneficial than reinventing the wheel with new language and organization. The U.S.

Navy is currently mandated to conform to ISO 17025 and hopes that NELAC will keep similar language for conformity.

A participant noted that laboratories who do industrial work want to strive to meet the ISO standard and if the Quality Systems standard and the ISO 17025 look similar it would be beneficial to clients who are already familiar with ISO 17025.

Mr. Siders questioned the attendees to see if anyone objects to the use of ISO 17025 language. There were no responses.

A participant stated that smaller laboratories should not be accountable for critical analytes which they do not analyze due to limited resources. Smaller laboratories do not usually have the dedicated QA staff to develop and implement plans around ISO 17025.

A participant stated that international accreditation will be helpful to larger laboratories who may do international work. She continued that the current standards are very hard to follow and training laboratory personnel is very difficult with the current organization of the current standard. If the standard is going to be changed to include language from ISO 17025 this would be a good time to reorganize it. The committee responded that several laboratories have mentioned difficulty in implementing the NELAC Standard according to the current organization and that perhaps organizing it the way an audit would be performed would be beneficial.

Another participant commented that smaller laboratories are as interested in the quality of their results as larger laboratories. Ms. Harding feels that the committee should push hard to meet with consistency between standards which would benefit all laboratories.

**PRESENTATION OF PROPOSED CHANGES TO PBMS**

Presentations were given by Dr. Harry Gearhart, Mr. Jerry Parr, Dr. Ken Jackson, and Mr. Bob Wyeth on suggested changes and recommendations by the Performance Based Measurement System (PBMS) Subcommittee. These presentations with proposed changes are included in Attachment D.

Dr. Gearhart presented changes concerning 5.10.3, 5.10.3.1, 5.9.4.2, and 5.10.2. Mr. Parr presented an overview of the changes to Appendices C and D and how they arrived at their changes. Two primary source documents were ISO 17025 and the U.S. Department of Agriculture (USDA)/Agricultural Marketing Service (AMS) Pesticide Data program. Dr. Jackson presented changes from Appendix C and Mr. Wyeth presented changes to Appendix D.1.

The subcommittee presented their future plans which will be offered to the Quality Systems Committee.

Mr. Siders began by recognizing the members of the PBMS subcommittee and thanking them for their work. He stated that all subcommittee work should come through the Quality Systems Committee. He also discussed that the term matrix has been changed to reflect the way that matrix has been used in Chapter 1, Program Policy and Structure.

Discussion

A participant asked whether the committee has considered providing guidance on how to establish method quality objectives (MQOs). The committee responded that the U.S. EPA has put together a training course and that it may be either client requested or as a standard set forth on the objective of the test.

In response to a suggestion about using a tiered approach to PBMS, the committee said that the subcommittee will discuss this. Concern was expressed about using this approach because it hides problems with the current methodology but does not buy us anything. Another participant felt that the tiered approach is a great idea, but that there are problems with terminology. She felt that ISO 17025 actually lends itself to a tiered approach but the term "mandated method" must be clearly defined and understood.

Dr. Carl Kircher led the discussion about Appendix C and how it was set up for one of the most basic tiers. A participant responded that the duplicates, spikes, and blanks are all necessary. Another participant asked how a specific problem would be handled. If the method detection limit (MDL) is .5, and the MCL was 1 and the result was .9 then the result would fail based on the current RPD even though the result should be acceptable.

It was also questioned whether the presentations by the subcommittee would be posted and how persons that were not present today would be able to submit comments. The committee responded that the presentations were just subcommittee reports and have not been reviewed by the Quality Systems Committee. At some point the PBMS subcommittee working closely with the Quality Systems committee may put their recommendations out for stakeholder review.

Dr. Simmons asked a question concerning 5.10.3.1 D – he interprets this to mean that the laboratory must receive advance approval by the client unless a modified method was used. A member from the subcommittee responded that this is not how this was intended.

In response to whether PBMS should be extended to radiochemistry, Dr. Jackson responded that this issue had not yet been addressed and perhaps it should be.

The comment was made that the terminology being used is getting to be a problem. The words calibration and data quality objectives (DQOs) are being used in different ways and everyone should be extremely careful on how they use these terms. We should be cautious that the terms used throughout NELAC are consistent with U.S. EPA and ISO dictionaries.

A participant suggested that the committee should be careful in tiering and his supports performance based limits. He suggested addressing the variation around the result at different concentrations and take care on applying the standards. Another participant suggested that there is more "statistical power" in analyzing 3 samples at low concentration, 3 at medium concentrations, and 3 at high concentrations. Dr. Wilson Hershey would like to put a strong vote against the presentation today of 3 low, 3 high, and 3 medium concentrations.

A committee member questioned why a saline matrix was left out under matrices. Dr. Jackson responded that matrices were chosen in an attempt to stay consistent with Chapter 1. The categories of matrices were left as simple as possible.

A participant suggested that the committee consider consulting legal counsel on how PBMS would fit together with the Daubert Principle which is based on court case/ruling that impact on what can be submitted as evidence in a course case. Most regulated laboratories will used federally regulated methods. Comparability is an issue that will have to be discussed.

**ADJOURNMENT OF SESSION 1**

Mr. Siders requested attendees with comments and proposed language to submit them in writing and adjourned the meeting.

**SESSION 2 - WEDNESDAY, MAY 23, 2001**

Mr. Siders began with introductions of new committee members. The new members are Ms. Betty J. Boros-Russo from the State of New Jersey and Mr. Bob Di Rienzo of DataChem Laboratories Incorporated. He gave an overview of the history of Quality Systems Committee and the preparation of Chapter 5 and then reviewed the agenda.

**PRESENTATION OF PROPOSED CHANGES TO APPENDIX D.1 (CHEMICAL TESTING)**

Mr. Charlie Hooper and Mr. Jeffrey Nielsen stated that the changes made to Appendix D.1 were an effort to separate method and laboratory performance from method and matrix performance. The floor was opened for discussion on proposed changes to Appendix D.1.

**Discussion**

A participant questioned the Evaluation Criteria #2 concerning method blanks as the current wording would cause routine data to fail. A committee member responded that none of the criteria would cause you to dismiss the data but would cause you to address the problem. Mr. Siders added that if the method blank result, the method detection limit, and the result reporting limit are close it may be something that the needs to be brought to the client's attention. A committee member pointed out that contamination may not be the problem and that there are other possibilities that may cause a problem, such as noise of instrument etc.

Another participant continued that Evaluation Criteria #2 would require large amounts of data to be flagged. A committee member added that he had no problems with flagging the data and agreed that the client needs to know, and that the samples should be flagged.

A participant suggested wording that would give that option that items #2 and# 3 would not be invoked at less than half the reporting limit.

An attendee shared results of a study by the Department of Defense (DoD) in which 20 or 30 laboratories submitted laboratory control sample (LCS) results and control limits were evaluated; 35% of these failed. Recommendations from their study suggested that there should be an allowance of some compounds to fall outside the acceptance criteria without failing for everything. He suggested that if there are greater than 10 spike compounds are used then 10% may be able to fall outside the limits before the LCS fails. He will submit suggested language. Another attendee stated that he had a statistician look at data – if there were 75 analytes how many are likely to fall outside acceptable limits? The statistician gave theoretical numbers on

the number of analytes which might be expected to fall outside of limits as the number of analytes within the sample rose. Mr. Siders asked that the attendees write up their proposed changes and submit them to the Quality Systems Committee.

A participant suggested that if even if a control sample contained numerous components, if the same component is out multiple times it should indicate that this is a problem.

A participant questioned the proposed changes to evaluation criteria concerning the individual LCS and the determination of acceptance criteria when not mandated in the test method. He asked if it is the committee's intent to allow a laboratory to use historical data and to only mandate when required by the test method or supplied by the client.

Another participant from a state agency added that there are times when the client may not supply limits when it is permitting work. The laboratory may be able to claim that they do not know the regulatory limits. He suggested that 5.11.2A be changed to require the laboratory to solicit the regulatory limit from their client. Mr. Siders responded that the committee has looked at this issue and that the laboratory should do what works for the client.

It was suggested that in under each section for Evaluation Criteria the word "should" be changed to "shall." Mr. Siders asked the committee if there were any reason why "should" was left in these sections. Mr. Siders stated that all instances of the word "should" will be changed to "shall."

A member of the subcommittee commented if a method blank is below method detection limit it would be reported as 0 and would not apply. Mr. Siders asked if this should be changed to actually say if below 0 then they do not need to be reported. The following new wording was suggested "...exceeds the detection limits and meets one of the following criteria." An unofficial poll was taken to see if attendees thought the new wording solved the problems.

An attendee suggested that this would not handle all situations. If concentrations were greater than 10X the method detection limit there would be no need for corrective action and it was suggested that it be one-half the reporting limit. Another attendee spoke in support of one-half the reporting limit.

An attendee commented that a laboratory must track performance over time in order to determine what the method can so that factors that contribute to varibility are identified.

Mr. Joe Slayton of the U.S. EPA, Region 3 suggested that the heading " Evaluation Criteria" be changed to "Evaluation Criteria and Corrective Action." The committee agreed.

A participant suggested the verbiage change for the LCS be limited to the preparation batch. The committee responded that what is currently written will not affect this and the total analytical system goes along with batches. If the LCS is out of control then the laboratory is out of control and data should be reprocessed or the data needs to be flagged.

The committee chair paused discussion to arrive at a resolution of the changes discussed to Appendix D.

Calculation Issue

The committee has decided to remove all calculations from the chapter. Under each of the sections "Evaluation Criteria and Corrective Action" the calculations would be removed and the sentence "The laboratory shall document the calculation for..." will be added.

A participant commented that it would be a good idea to remove calculations. Laboratories may have slightly different ideas on calculating the percent recovery and the calculations supplied are overly simplified and there is a multiplicity of different ways to calculate the percent recovery, all of which are valid

She also questioned whether a matrix spike could be used in lieu of the LCS as the new wording has removed this opportunity. The committee suggested moving a previously stricken note and adding it under positive controls to solve this issue.

A participant said that matrix spike duplicates can be an issue when near detection limits and that absolute limits can be used. Another participant added that replicate analysis below quantitation limit does not give relevant information and the only way to get usable information when results are below detection limits is to use duplicate spikes. Mr. Siders responded said the current verbiage does not limit the laboratory from using additional control samples to measure precision. There is currently nothing that forces the laboratory to do these matrix spike duplicates above the quantitation limit. It was agreed that if you are going to get useful information for data with matrix spike duplicates they must be above the quantitation limit.

Another participant stated that if a laboratory is analyzing drinking water there are many analyses that do not have performance criteria so they use laboratory criteria. They use a data qualifier. If the standard does not specify the criteria for establishing performance criteria then laboratories are not on equal footing when they are making decisions on accepting or rejecting data. The committee responded that to handle these situations you would have to be too prescriptive. .

It was suggested by a participant that if matrix duplicates are a "should" rather than a shall then the committee should consider removing this section. The question of letting the standard be the bare minimum was raised and could an auditor hold you to doing these. The committee responded that matrix duplicates are not required but it is required that the laboratory consider the need for the matrix duplicate. An auditor would not require you to do these but may ask if your laboratory made the decision on matrix spikes and duplicates as a function of the project you are involved in. The matrix spike and duplicate information is required in the case when a laboratory is substituting these for the LCS.

Mr. Siders had to end discussion on this topic in order to keep to the agenda. Several committee members and attendees were asked to work together and provide the agreed upon changes to the text.

Proposed Changes to Page 2, Evaluation Criteria

Discussion ensued on proposed changes to page 2 of 16, Evaluation Criteria, first paragraph, last sentence. An attendee gave the following example "analyte result of 1, reg limit of 4, blank

measurement = .5 then the measurement would fail." The committee contended that the current verbiage would only make you qualify or reprocess the data. If you change it to "exceeds the greater,"it may open it up to interpretation to the greater of each.

Mr. Siders polled the committee to determine if they agreed that the terminology should be changed to read "the greater of the following."

A participant added that if the change is accepted, then a measurement error of ±10% at the minimum has been introduced. Another participant agreed that this could happen but since we must analyze at low concentrations it cannot be avoided.

He and several committee members agreed to confer and work out wording to present to the committee.

He also questioned the terminology concerning control limits and if the mandated method has less stringent criteria than the laboratory control criteria which should be used. The committee responded that even if method has mandated criteria, if the method has less stringent criteria than the laboratory then the laboratory can use their criteria. No changes were made to the current text.

The third issue he presented was if a large number of compounds are spiked there may be several compounds which are outside their acceptable limits. Under the current conditions the laboratory would have to qualify or reprocess the data. Several participants felt that this is unfair because the more analytes the laboratory is testing for the more likely they are to have several which fall outside acceptable limits and all the data should not have to be qualified or reprocessed. Mr. Slayton responded that using statistics to calculate a number that could fail and be acceptable brings up an entirely new discussion. He also added that allowing a specific number to fail would allow a laboratory to not notify a client even if a specific analyte they wanted analyzed was outside control limits.

The question was raised that if auditors will be using the standards as a basis, could they hold the laboratories responsible for reprocessing? The committee responded that the current verbiage allows the laboratory to deal with this now and the terminology will be revisited next year.

Other Suggestions

One participant would would like to see a data qualifier included. Another participant suggested deleting 5 words, "consider suspect and the samples"on page 4 of 16, top paragraph.

**ASBESTOS SUBCOMMITTEE**

Mr. Mike Beard of Research Triangle Institute gave an overview of the Asbestos Subcommittee's work. Overheads for this presentation is included in Attachment F.

**PROPOSED CHANGES TO CHAPTER 5 (BODY OF TEXT)**

Mr. Siders presented proposed changed to Chapter 5:

**5.9.4.2.1 Initial Instrument Calibration**
It was pointed out that "can be demonstrated" is a wide open issue. The participant stated that he has had difficulty obtaining documentation from manufacturers showing independency of lots. Dr. Siegelman responded that this is a common problem and this was put in to guide the laboratory to perhaps use a different manufacturer or make the manufacturer document that this is a separate lot.

**5.10.2**

Mr. Siders discussed on a question that came up at the Sixth NELAC Annual Meeting (NELAC 6) on how to demonstrate capability. "How would a laboratory show that a new instrument is functioning properly?" This was put back on the agenda as an issue to be resolved.

**5.13f**
No comments were made concerning the proposed change.

**5.14.b**

The proposed change was received from the Accrediting Authority Committee. The change was suggested because it may be restrictive and place a burden on laboratories if they can only subcontract to laboratories with NELAP accreditation.

**PRESENTATION BY MICROBIOLOGY SUBCOMMITTEE (APPENDIX D)**

Ms. Marty Casstevens began by introducing the members of the Microbiology Subcommittee and thanking them for their participation. The floor was opened for discussion on any questions concerning changes to Appendix D.

An attendee suggested that the wording in Section D.3.1 sounds as though there should be no growth at all. A member of the subcommittee suggested changing "and" to "or" on the second line to correct the problem.

A committee member asked whether laboratories could purchase these cultures for running positive controls as opposed to preparing their own. The subcommittee responded that it is possible for laboratories to purchase cultures but the laboratory should maintain positive cultures.

A participant stated that he has seen that there may be large numbers of negatives when positive controls are not maintained in the laboratory. He added that sterility checks should be done on each batch, not lots. The committee says to do at least one container per lot. The laboratory can do more if their laboratory criteria requires more.

Another participant stated that sterility checks on vessels can be very costly for laboratories. Vessels within a lot do not show large amounts of variation. Dr. Irene Ronning of the subcommittee answered that these guidelines came from U.S. EPA guidelines. The issue would be if the NELAC Standard should be more stringent than U.S. EPA's guidelines.

With regards to Section D.3.1.2 it was questioned whether you have to do a sterility check at the beginning and end of a funnel or series. The U.S. EPA training manual says that you must do it after each funnel, whereas some laboratories do sterility checks at the beginning and end of a series. Another participant suggested that the problem with doing every 10 on the manifold could cause several samples to be invalidated when they were not run through the same filter. Mr. Siders suggested that the subcommittee work together with the new certification wording to prepare new language.

**Proposed change to D.3.1**

A participant asked if a laboratory must maintain samples of negative controls to which the committee responded that there are one-time use negative controls available from manufacturers.

Another participant asked if two cultures are supposed to be grown on the same plate. The committee responded that they were suggesting that two cultures be grown on the same plate to avoid duplicates. You cannot do replicates on samples below detection limits. Mr. Slayton asked that the wording be changed from same sample to same plate; the committee accepted the proposed changes.

**D.3.3 Method Evaluation**

A participant questioned the meaning of the term "a sufficient number" and could there be more guidance. The committee responded that the laboratory must make their own guidance.

It was suggested by another participant that they use five samples to demonstrate proficiency but the committee felt that it would be better to keep ten. The subcommittee was using an in-house proficiency test (PT) so that if there were more than one or two microbiologists doing the analyses the laboratory would not have to purchase numerous PT samples.

**D.3.4**

It was asked if there are other tests that could be done for verification that would not require preparation of heat sensitive media. Ms. Ronning responded that there are numerous different types of verification and the problem arose on how to simplify wording and the verification is dependent on the method you are using.

A participant stated that checking the quality of water each month may be a problem if there is a change to the water treatment system. The question was asked if this section meant that you could not buy the materials dehydrated. In response to a question regarding making the materials in the laboratory versus buying them commercially, Ms. Ronning stated that U.S. EPA has said that if it is available commercially do not make it up in the laboratory. The committee added that perhaps wording should be added to say if you can make it better than what can be purchased you should be allowed to make your own. Ms. Ronning stated that the U.S. EPA will not allow this and read from the U.S. EPA Standard Methods Section 9020, "... when available media should be purchased."

Another participant stated that there is often more than one standard method that can be used. You can use another standard does not exclusively say that you must buy the media. Ms.

Ronning stated that there are different standards but that the subcommitte is trying to get a standardized method for microbiologists.

A participant commented that laboratories in New Jersey that were requested to purchase media had never declined. She also questioned when they were going to update the laboratory certification manual. Ms. Ronning stated that new methods should be added to the U.S. EPA's Laboratory Certification Manual. Ms. Carol Madding added that the manual is being updated and the wording will probably be left the same.

Mr. Bennett Osborne of the Microbiology Subcommittee disagreed on making guidelines more stringent, as this is against NELAC goals. After some discussion on how stringent the standards should be it was decided to leave terminology as is.

**D.3.6**

A participant stated that the bacteriological Water Quality Test was too difficult for some laboratories. The committee replied that if the test is too difficult then they should send it out. It was included because it is in the Federal Drinking Water Standards.

**D.3.7a)**

The committee responded that you must reslant after every five to the question that if you buy a reference culture, do you have to reslant after every five. Another participant asked whether it was five sequential days or five sequentially cultured. The answer is sequentially cultured.

**D.3.8.b.2**

Mr. Slayton stated that D.3.8.b.2i states that pressure cookers shall not be used for sterilization of media. Has media been defined? The committee stated that their thought was that the sterilization of dilution water is not included in this.

A participant continued with discussion on calibration of equipment such as thermometers. One year calibration for many instruments may be too little some and too often for others. The committee was polled as to whether they wanted to change the terminology. The consensus was that the terminology requires at least one a year but the laboratory can choose to do more.

Another participant questioned how one calibrates a gravimetric pipet tip. Ms. Marlene Moore stated that the Laboratory Certification Manual requires calibration of the micro pipetor, not the tips. It was pointed out by another participant that micro pippette tips do vary.

The question was asked why the autoclave records require the pressure be recorded especially since many autoclaves do not have pressure gauges? The committee responded that most media actually have temperature and pressure specified.

It was also asked how the U.S. EPA's Laboratory Certification Manual is used in the NELAC Standard. The committee responded that the NELAC Standard must be as stringent as the U.S. EPA's Laboratory Certification Standards and that NELAP accreditation will be accepted as equivalent to U.S. EPA certification..

**D.2.1.a.2.iii**

A participant expressed concern with the entire paragraph. If only looking at 20 data points how can you do an accurate control chart? He maintains that there should be different scales of control charts. One on a smaller scale such as analyst, air temperature etc. while the other takes into a consideration a longer period of time. The committee responded that the 20 data points represent two years. If you have more than two years you will have the control chart heavily weighted so that error over a short term cannot be noted. The participant countered with the argument that you cannot supply enough information only over the short term. The committee responded that the 20 comes from U.S. EPA guidance. Explaining that if you have had a long term decline it will eventually show by missing the PT. Another participant added that if you are looking at short term and long term the standard deviations should become closer over a period of time.

**D.2.8i**

Mr. Mike Tucker of U.S. EPA Region 7 stated that they cannot do a chronic test for every batch. He explained that they prepare new batches every three weeks and it would be extremely time consuming to do chronic testing with every batch. A committee member responded that laboratories do see differences between batches. Perhaps it would be possible to verify that each of the components is good and only do a tox test when a new batch of food is ordered. Mr. Siders stated that if laboratory data clearly demonstrate there is no problem then this requirement is not necessary. Mr. Siders asked that a subcommittee member and the Mr. Tucker work together to prepare new wording.

**D.5 Air Testing**

There were no comments from the floor.

**ADJOURNMENT**

The allotted time having expired, the meeting was adjourned.

**Attachment A**

**ACTION ITEMS**
**QUALITY SYSTEMS COMMITTEE MEETING**
**MAY 22-23, 2001**

| Item No. | Action | Date to be Completed |
|---|---|---|
| 1. | Finish integration of ISO 17025 and PBMS language in Chapter 5 | Oct. 2001 |
| 2. | Finish Asbestos Testing Appendix | Oct. 2001 |
| 3. | Obtain further direction on ISO 17025 integration and PBMS from Board of Directors | As Needed |
| 4. | Solicit NELAC stakeholder ISO 17025, PBMS, and Asbestos drafts prior to NELAC 7i | |

**Attachment B**

## PARTICIPANTS
## QUALITY SYSTEMS COMMITTEE MEETING
## MAY 22-23, 2001

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**Attachment C**

# NELAC 7 ISO 17025 COMBINED PRESENTATIONS
# DR. FRED SIEGELMAN AND MS. MARLENE MOORE
# QUALITY SYSTEMS COMMITTEE MEETING
# MAY 22-23, 2001


## NELAC Quality Systems
## NELAC VII Annual Meeting
## May, 2001

Fred Siegelman
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## Agenda

- Introduction to NELAC, Guide 25 and ISO 17025 - Fred Siegelman
- Measurement Uncertainty - Marlene Moore
- Efforts to change the NELAC standard - Fred Siegelman
- Discussion
- Poll meeting attendees for preferences

## NELAC, Guide 25 and ISO 17025
### A Short Trip Down Memory Lane

- Where have we been?
- Where are we now?
- Where are we going?
- When will we know that we are there?

## History

- Committee on National Accreditation of Environmental Laboratories (CNAEL) 7/91-7/92
- State-EPA Focus Group 1/93-9/94
- National Environmental Laboratory Accreditation Conference (NELAC) 2/95 - *ongoing*

## NELAC History

- Proposed Standards - FRN 12/94
- 1st Annual meeting (2/95)
  - Adopted Constitution & Bylaws
- 2nd Annual Meeting (7/96)
  - Adopted 70% of 4 chapters
- 3rd Annual Meeting (7/97)
  - Adopted complete set of standards
- 4th Annual Meeting (7/98)
  - All proposed changes adopted
- 5th Annual Meeting (7/99)
  - First round of Accrediting Authorities recognized
- 6th Annual Meeting (6/00)
  - Changes adopted

## NELAC Quality System Commitments

- NELAC's commitment to Performance Based Measurement Systems (PBMS) - flexibility
- NELAC commitment to international consensus standards. - ISO/IEC Guide 25 and ISO 17025

## Goals

- Improve overall quality of compliance data via NELAC/NELAP
- Improve present NELAC Quality Systems standards
- Further utilize PBMS concepts
- Utilize ISO/IEC 17025 standard
- Adhere to Quality Systems Committee's Guiding Principles

## NELAC and ISO 17025

- NELAC Quality Systems present standard based on ISO Guide 25
- ISO/IEC 17025 replaced ISO Guide 25
- Integrate ISO/IEC 17025
- ISO/IEC 17025 - ANSI Copyright Issue
- Quality Systems Committee formed ISO 17025 Subcommittee

## ISO 17025 Subcommittee

- Robert Di Rienzo, DataChem Laboratories.
- Betsy Grim, U.S.EPA.
- Donald Lore, State of Utah.
- Barbara McCleary, State of Delaware.
- Marlene Moore, Advanced Systems, Inc.
- Randall Querry, A2LA.
- Fred Siegelman, U.S.EPA.
- Mary Wisdom, U.S.EPA.

## ISO/IEC 17025 History

- General requirements for the competence of testing and calibration laboratories
- Approved in 1999
- Replaced third edition of ISO/IEC Guide 25:1990

## ISO/IEC 17025

1 Scope
2 Normative references
3 Terms and definitions
4 Management requirements
5 Technical requirements
Annex A Cross-references to ISO 9001:1994
Annex B Guidelines for establishing applications for specific tests

## ISO 17025 New Requirements

- Consistent with ISO 9000 series standards
- Identification of potential conflicts of interest
- Service to clients
- Preventive action
- Uncertainty procedures for testing


## Measurement Uncertainty
for Environmental Programs

Marlene Moore
Advanced Systems, Inc.
May 22, 2001

## Terms

- Definitions
  - Absolute uncertainty
  - Relative uncertainty
  - Uncertainty of measurement
  - Expanded uncertainty

## Does not include

- Blunders
  - Quality system
    - quality assurance
      - quality control

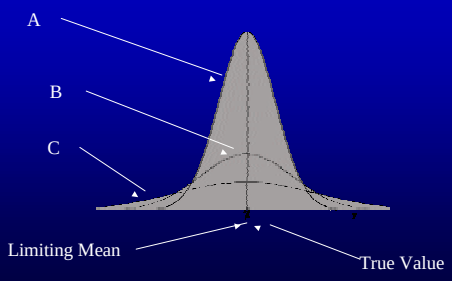
## What is Uncertainty

- The range of values that could reasonably be attributed to the measured quantity
- The level of confidence that the value actually lies within the range defined by the uncertainty interval
- Or simply - the interval about the result

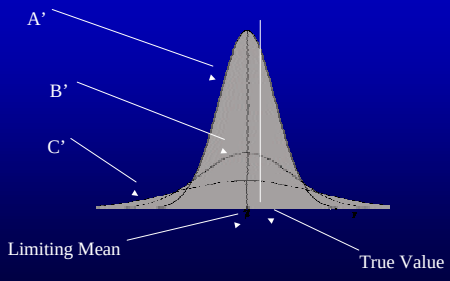
## Formulas

- Error = Result - True Value
- Error is the result of Random Error (imprecision) + Systematic Error (bias)
- Random Error = Result - Average result
- Systemic Error = Average - True value

## Unbiased




## Biased




## Expression

- Measurement ± standard uncertainty
- Measurement ± combined uncertainty
- Measurement ± expanded uncertainty @ 95% confidence level

## Sources of imprecision (Type A)

- Instrumental instability
- Environmental fluctuations
- Operator skill
- Reagent control
- Variability of blank, sample
- Variable contamination, losses
- Faulty technique
- Maintenance of tolerances

## Sources of bias (Type B)

- Calibration
- Operator bias
- Uncorrected blank
- Inefficiencies losses
- Tolerances adjustments
- Interference resolution
- Contamination gains
- Instrumental shifts
- Matrix effects
- Theoretical

## Uncertainty Evaluation

- Good professional practice
- Provides information about quality and reliability of the result
- Expected to reduce client/lab misunderstandings in the future
- Degree of rigor based on use

## Method Uncertainty

- LCS
  - Includes all components
  - Straight forward
  - Uses existing data
- Laboratory only
  - ISO/IEC 17025 requirement

## Measurement

- Method Uncertainty
  - Does not define measurement uncertainty
  - Does not address sample
  - Does not address sampling
  - Does not address uncertainty of average value for site or compliance

## Expanded Uncertainty

$$U = k\, u_c(y)$$

$u_c(y)$ = Combined Standard Uncertainty

$k$ = Coverage Factor

## Uncertainty

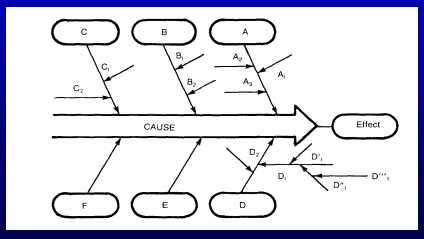
$\overline{X} \pm U$ 95% confidence level, k- 2

Where, $\overline{X}$ = the mean of *n* measurements

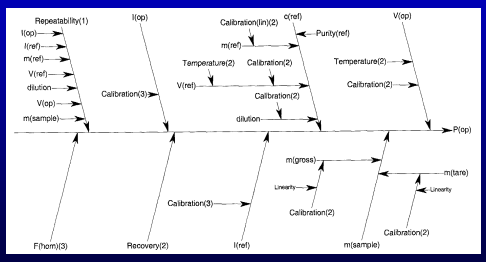
U = the uncertainty

k = the coverage factor for a confidence level of approximately 95%

## Cause Effect Diagram



## Eurachem Document



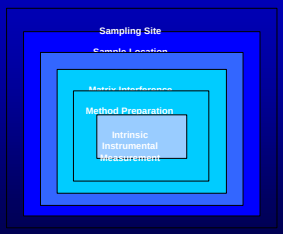

## Nested Uncertainty

- New concept
- Environmental programs
- Estimate of uncertainty based on single measurement
- Incorporates sampling and laboratory effects

## Quality Control samples

- More than laboratory control samples
- Matrix
- Field split duplicate samples
- Co-located replicate samples

## NESTED Approach



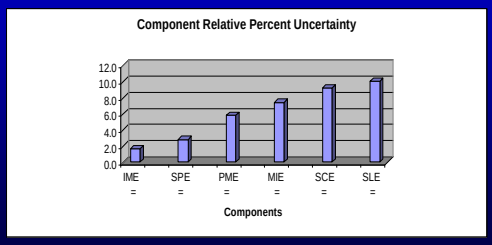

## Sources of Uncertainty

| Uncertainty Sources | Source Symbol | Analytical Sample | Analytical Sample Symbol |
|---|---|---|---|
| Intrinsic (Instrumental) Measurement Effects | IME | Instrument Calibration Standard | ICS |
| Spike Preparation Effects | SPE | Initial Calibration Verification Standard | ICV |
| Preparation Method Effects | PME | Laboratory Control Sample | LCS |
| Matrix Interference Effects | MIE | Matrix Interference Sample<br>Matrix Spike/ Duplicate Sample | MS<br>MS/MSD |
| Sample Collection Effects | SCE | Field Replicate (Duplicate) Sample (Collected from same location and during same sampling event time) | FSR |
| Sample Location Effects | SLE | Co-Located (Same Location) Sample (Collected 0.5 – 3 feet away from field sample) | CLR |
| Sampling Site Media Effects | SSE | Site field sample collected from the environmental site for the study | SFS |

## Quality control samples

- Instrument calibration standards (IME)
- Spike Preparation effects (SPE)
- Preparation Method effects (PME)
- Matrix Interference effects (MIE)
- Sample collection effects (SCE)
- Sample location effects (SLE)

## Measurement Uncertainty




## Result Expression

- Result:

  50 ug/Kg
- Uncertainty interval:

  36- 64 ug/kg at 99% CL
- Corrected for systematic error:

  40 - 70 ug/kg at 99% CL

## Unique approach

- Does not estimate uncertainty by combining component standard uncertainties
- Uses the combined standard uncertainties of QC samples to estimate component standard uncertainties
- Component uncertainties are combined, normalized and expanded to estimate the uncertainty with a single test measurement.

## Assumptions

- Normal distribution
- Statistically independent
- Uncertainties are proportional to the analyte value
- Relative uncertainty is constant
- Components are multiplicatively combined
- Uncertainty samples is a combination of component uncertainties

## Uncertainty Expression

- Provides quantitative expression for comparability
- Provides graphics for identifying uncertainty components
- Provides statistical assessment of data during planning (DQO) and final decision making (DQA)

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## Options to Change the NELAC Standard

NELAC, Guide 25 and ISO 17025 Change Is Coming

## Alternative Types of Standard

- An Independent NELAC standard without relationship to any international standard
- A NELAC standard consistent with an international standard: ISO 17025

## The Alternatives Facing Us

- Text of a standard consistent with ISO 17025 (copyright issue)
  - ISO 17025 language incorporated by reference
  - NELAC standard includes ISO language
  - ISO 17025 language used in a checklist
- Organization of a standard consistent with ISO 17025
  - organized to follow ISO 17025
  - organized to follow present NELAC organization

## Current Activities and Direction

- ISO/IEC 17025 Integration:
  - Comparison Spreadsheet (ISO/IEC 17025, ISO Guide 25, NELAC Chapter 5)
  - Identify ISO Guide 25 language in present Chapter 5
  - Integrate NELAC Chapter 5 and ISO/IEC 17025 text and address format issues
  - Leave space for PBMS Subcommittee product

## Example of Comparison of NELAC,guide 25 and ISO 17025

4.2.2 The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

NELAC 5.1 a) The elements of this quality system shall be documented in the organization's quality manual. (25-3.1)

NELAC 5.2 Quality Manual

The quality manual and related quality documentation shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard. (25-3.2)

The Quality Manual shall list on the title page: a document title; the laboratory's full name and address; the name, address (if different from above) and telephone number (including area code) for the laboratory, the name of the quality assurance officer (however named); the identification of all major organizational units which are to be covered by the quality manual and the effective date of the version;

The quality manual and related quality documentation shall also contain: (25-3.2)

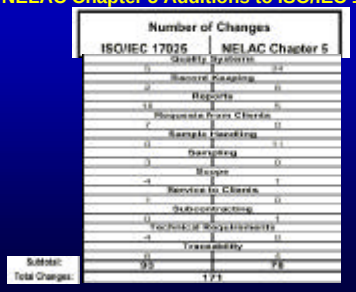
## Changes to NELAC Chapter 5

**New Additions from ISO/IEC 17025**
**NELAC Chapter 5 Additions to ISO/IEC 17025 Format**

## Changes to NELAC Chapter 5

**New Additions from ISO/IEC 17025**

**NELAC Chapter 5 Additions to ISO/IEC 17025 Format**




## Rearrange Chapter 5 to ISO/IEC 17025 - Pros

- **Better organized, separates administrative from technical requirements.**
- **Consistent with international lab standard allowing easy review by international body. NELAC Chapter 5 will gain international acceptance if formatted similar to ISO 17025.**
- **Allows order change for better organization of the assessment process.**
- **Allows change in future to be easier. We don't expect significant or drastic format changes to ISO/IEC 17025 Standard.**
- **Improves chances for acceptance and approval by other auditing agencies.**
- **Incorporates ISO 9001 into NELAC Chapter 5.**

## Rearrange Chapter 5 to ISO/IEC 17025 - Cons

- Accrediting Authorities and laboratories that have organized their regulations and QAPP to current NELAC Chapter 5 will have to modify these. State accreditation rules and checklists written in NELAC format require modification.
- Lots of change, but this will happen anyway as we integrate ISO/IEC 17025 into existing NELAC format.
- Must provide users with a cross-reference list from old to new formats.

## Maintain Chapter 5 Pros

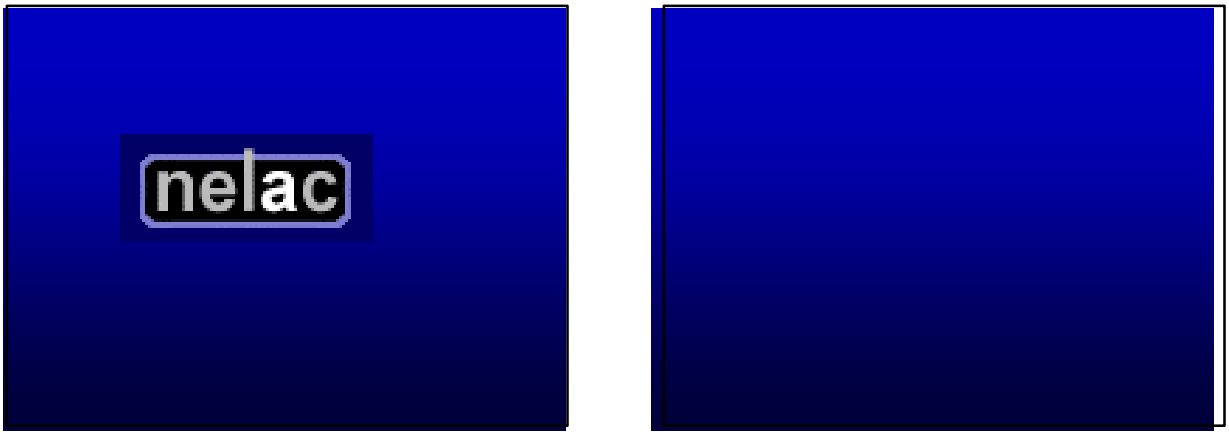
- Maintains order accepted by users now. Or little change.
- Limits sections to 16 with appendices.
- Accrediting Authorities and laboratories that have organized their regulations and QAPP to current NELAC Chapter 5 will not have to modify these. State accreditation rules and checklists written in NELAC format won't require modification.

## Maintain Chapter 5 Cons

- Current order confusing.
- Current order overlaps issues in too many sections, such as QC in Section 5.6 and 5.10 and appendix D. supplies ordering in 5.10.7 and 15.2.
- Placement of new sections in NELAC Chapter 5 will cause significant modification and disruption to existing Chapter 5. Unclear where new concepts in 17025 will be added, such as uncertainty, purchasing, contract review.
- Requires cross-reference listing from current standard to 17025 organization, which will allow easier identification of 17025 requirements by international bodies and users.
- Will make NELAC significantly harder to evaluate internationally.

## The Time Has Come to Decide.

- What type of Standard?
- How will it be structured?
- How will it be organized?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**Attachment D**

# PROPOSED CHANGES TO PBMS
# PRESENTATIONS GIVEN BY DR. HARRY GEARHART, MR. JERRY PARR, DR. KEN JACKSON, AND MR. BOB WYETH
# QUALITY SYSTEMS COMMITTEE MEETING
# MAY 22-23, 2001

# PERFORMANCE BASED MEASUREMENT SYSTEM

## STANDARDS IMPLEMENTATION MODEL FOR PERFORMANCE BASED MEASUREMENT SYSTEMS

Quality Systems PBMS Subcommittee

## Current Drafts for Consideration

- Revise NELAC Standards Ch. 5
  - integrate PBMS concepts into lab policy & practice
- Restructure Ch. 5, Apps. C & D.1 as "how-to" guides for lab measurement system evaluation
  - initial evaluation
  - ongoing evaluation
- NELAC approach does not address DQO responsibilities of regulated entities

## General Approach

- Use of Test Methods (5.10.3)
  - Demonstrate the measurement system provided data consistent with the intended use
    - acceptable initial evaluation
    - acceptable calibration
    - documented ongoing evaluation

## Method Selection

- 5.10.3.1
  - When use of a method is mandated by a regulatory agency, or is specified by the client, only that method may be used
  - In other cases, alternative methods may be selected
    - Must provide data quality to meet client needs & be client approved
    - Recommendation for alternate methods:
      - standardized methods
      - lab methods

## Method Evaluation

- 5.10.3.2
  - MQOs are the focus of evaluation
  - goal is "determine and document performance of measurement system *re* materials being tested"
  - MQCs are determined for:
    - precision & bias
    - sensitivity
    - selectivity
  - MQCs must meet MQOs

## Calibration (5.9.4.2)

- Instrument Calibration
  - no. of points determined by method
  - if no method mandated, refer to MQOs
  - if single point & blank used (e.g. ICP), demonstrate linearity, sensitivity, and accuracy
  - used for quantitation
- Calibration Verification
  - independent source
  - frequency
  - used to verify

# PERFORMANCE BASED MEASUREMENT SYSTEM

## Laboratory Methods Manual

- 5.10.2
  - SOPs cover
    - lab activities
    - test methods
    - document storage
  - Test method SOPs follow EMMC 17 points

## Policy into Procedures

*The Devil is in the Details*

How did we get to Appendices C and D?

## Source Material

- EPA OW Streamlining Proposed rule
- Other EPA PBMS Guidance
- ELAB Reports
- GIES Report
- ASTM draft standard
- Draft IUPAC Harmonized Guidelines for Single Laboratory Validation of Methods of Analysis
- **17025**
- **USDA/AMS Pesticide Data Program**

## General Comments

- Most source material too academic
- Focus was generally "validation" of method for general use
- This effort designed to focus on specific lab use
- USDA program viewed as most relevant

## Restructuring of Appendices C and D.1

- Appendix C only method evaluation
  - Analyst proficiency addressed elsewhere
- Appendix D only QC
  - Validation, selectivity, sensitivity sections moved to Appendix C

## APPENDIX C

Initial Measurement System Evaluation

**Minimum required to evaluate the measurement system AS USED in the lab doing the evaluation**

**When required:**

1. **New methods**
2. **Modified methods**
3. **Sample-specific modifications (maybe)**
4. **Additional analytes (maybe)**

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catalyst@eazy.net ▲ www.CatalystInfoResources.com

# PERFORMANCE BASED MEASUREMENT SYSTEM

## MQOs and MQCs

**Criteria:** **Bias; Precision; Sensitivity**

**MQOs:**

1. **Provided by the client**
2. **Characteristics of standard methods**
3. **Based on initial evaluation**

**Method acceptable if MQCs equal to/better than MQOs**

## Matrix and Sample Type

**Matrix:** **Drinking Water; Non-Potable Water; Solid & Chemical Materials; Biol. Tissues; Air & Emissions**

**Sample Type:**

1. Perform the evaluation on the most difficult sample-type; e.g., a highly polluted waste water – can then apply to "cleaner" waste-water and drinking water. Or……
2. Perform the evaluation on site-specific samples

## MQCs

1. **DL; QL**
2. **Bias; Range; Precision**
   a. **At the QL: 3 samples**
   b. **At the mid-point : 4 samples**
   c. **At the UL: 3 samples**

   **On each set, measure recovery and precision**
3. **Selectivity**

## Initial vs Ongoing

- Appendix C: Initial Evaluation
  - whether or not a particular measurement system is suitable for an intended purpose
- Appendix D: Ongoing Evaluation
  - to document the performance of the method on actual samples

## Appendix D

**ESSENTIAL QUALITY CONTROL REQUIREMENTS**
**D.1 CHEMICAL TESTING**

&
COMPARISON TO PROPOSED Appendix D.1

## METHOD BLANK

- 1 MB/Prep Batch/Matrix Type
  Same (not to exceed 20 samples/batch/matrix)
- [MB] < 1/10 [S]
  Same
- [MB] < [S] and < 1/10 [Regulatory Limit]
  Same
  [MB] < QL
- Re-process the batch or appropriately qualify the data
  Same

# PERFORMANCE BASED MEASUREMENT SYSTEM

## Laboratory Control Sample

1 LCS/Prep Batch (20 sample limit)/Matrix Type
- Same

Include all reportable compounds (unless method states differently) except for interfering compounds or long lists
- Same but speaks to representative as opposed to all reportable compounds

For long lists, must insure representative (minimum of 10%) spike chemistries, elution patterns, masses
- Same criteria for selection; provides more detail and specifically states the number of spike compounds for given number of compounds of interest

Spikes maybe permit specified or client required
- Same

Rotate spike compounds to include all over a two year period
- Same

Used to assess the batch; does not indicate any other criteria for use
- Proposed language also speaks to LCS as assessing the batch but presents more detailed evaluation criteria including data being qualified where appropriate

## Matrix Spikes

1 MS/20 samples over time/Matrix Type
- Frequency determined as part of the planning process or as specified by required test method

Rotate samples selected for MS
- Not specifically stated

Can be substituted for LCS
- Not permitted

Include all reportable compounds (unless method states differently) except for interfering compounds or long lists
- Same

For long lists, must insure representative (minimum of 10%) spike chemistries, elution patterns, masses
- Same criteria for selection; provides more detail and specifically states the number of spike compounds for given number of compounds of interest

Spikes maybe permit specified or client required
- Same

Rotate spike compounds to include all over a two year peripd
- Not specifically stated

Poor performance may indicate sample problems and shall be reported to client
- Proposed language the same but presents more detailed evaluation criteria including data being qualified where appropriate

## SURROGATES

Required for use in all organic chromatography methods and for all samples, blanks, etc.

Same

Poor performance may indicate sample problems and shall be reported to client

Proposed language the same but presents more detailed evaluation criteria including data being qualified where appropriate

## MSD / MD

1 MSD or MD/20 samples/Matrix Type/Prep Batch

Frequency determined as part of the planning process or as specified by required test method. If not specified, 1 MSD or MD/20 samples/Matrix Type/Prep Batch

Poor performance may indicate sample problems and shall be reported to client

Proposed language the same but presents more detailed evaluation criteria including data being qualified where appropriate

## METHOD EVALUATION

| | |
|---|---|
| Demonstration of Analytical Capabilities | Reference 5.10.2.1<br>Same reference |
| Calibration | Reference 5.9.4<br>Speaks to calibration but does not reference specific section |
| Proficiency Testing | Reference 5.4.2.j & 5.5.3.4<br>Speaks to requirement but does not reference specific section |

## DETECTION LIMITS

✓ Appropriate for intended use or as mandated, must include all steps of the process/test method
- ✓ See Appendix C .. same

✓ All compounds (except where no spiking solutions available)
- ✓ See Appendix C .. same

✓ All test methods
- ✓ See Appendix C .. same

✓ All matricies
- ✓ See Appendix C .. same

✓ Re-determined with any relevant change in test method affecting performance or change in instrumentation affecting sensitivity
- ✓ Same requirement but also include requirement to be at least annual; annual requirement also applies to QL

✓ Must define relationship between DL and QL
- ✓ See Appendix C .. same; give specific examples and options

✓ Test methods must have established QL's greater than DL's
- ✓ See Appendix C .. same

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# PERFORMANCE BASED MEASUREMENT SYSTEM

**DATA REDUCTION**

✓Processes must be documented

✓ Not addressed in proposed document

**QUALITY OF STANDARDS AND REAGENTS**

Standards Reference 5.9.2

✓Not addressed in proposed document

Reagents, if not specified, at least reagent grade; document

✓ Not addressed in proposed document

Method suitable water quality to be monitored and documented

✓ Not addressed in proposed document

Verifiy titrants per written laboratory procedures

✓ Not addressed in proposed document

**SELECTIVITY**

✓ Absolute and Relative Retention Times evaluated and documented

✓ Same

✓ Chromatographic resolution verified and documented

✓ Same

✓ Confirmation required for unknown samples

✓ Same

✓ Documented instrument tuning

✓ Same

**CONSTANT AND CONSISTENT TEST CONDITIONS**

✓ Assure equipment operating within specifications appropriate to method

✓ Same

✓ Glassware cleaning procedures documented and verified to insure appropriate sensitivity

✓ Same

## Summary of Draft

- Initial method evaluation used to:
  - Document that measurement system (lab + method) capable of providing data fit for intended use in typical matrix
- On-going method evaluation used to:
  - Document performance of method on actual samples
  - Demonstrate measurement system control

## Next Steps (1)

- **Revision of Standard**
  - Collect comments on proposed draft and revise appropriately
  - Develop Certification Form and/or other language to address analyst proficiency
  - Coordinate with ISO 17025 effort
  - Have new language developed by NELAC 7i
  - Request other NELAC committees to integrate PBMS by NELAC 8
  - Vote on standards language at NELAC 8

## Next Steps (2)

- **Training**
  - Conduct training for AA auditors at NELAC 8
- **Communication**
  - Build support for new model (presentations, articles, etc.)
  - Enlist help of other organizations
  - Formal contact with EPA during the Fall of 2001 to communicate NELAC activity on PBMS

## Recommendation

Establish an Implementation Work Group to continue this effort reporting to the NELAC Chair